

Notice of Allowability	Application No. 09/493,353 Examiner Jeanine A Goldberg	Applicant(s) LINNEN ET AL. Art Unit 1634
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to 2/5/03.
- The allowed claim(s) is/are 1-13, 27-39, 43-50 and 54-61.
- The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - All
  - Some\*
  - None of the:
    - Certified copies of the priority documents have been received.
    - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - The translation of the foreign language provisional application has been received.
- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS must be submitted.
  - including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - hereto or 2)  to Paper No. \_\_\_\_\_.
  - including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

- DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

<input type="checkbox"/> Notice of References Cited (PTO-892)	<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	<input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.
<input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.	<input type="checkbox"/> Examiner's Amendment/Comment
<input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	<input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	<input type="checkbox"/> Other

#### **DETAILED ACTION**

1. This action is in response to the amendment filed February 5, 2003.
2. Claims 1-13,27-39,43-50 and 54-61are pending.

#### **REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance.

In view of the amendment filed February 5, 2003 and the terminal disclaimer filed disclaiming 09/494,332, Claims 1-13,27-39,43-50 and 54-61are allowable.

The claims are drawn to methods which require using oligonucleotide primers specific for the 5' noncoding region of HCV. In the specification Applicants have provided comparison results for the 5' NCR primers of the present invention and the Roche assay. Applicants have compared the primer pair SEQ ID NO: 1, 4 and SEQ ID NO: 2,7 with the Roche primers. It is noted that applicants have not provided the exact Roche primers which were compared.

Applicants have shown that the instant primer pairs detect more positive results than the Roche primers. Since it is presumed that the positive results detected were samples which were infect infected, the instant primer pairs (SEQ ID NO: 1 and 4 and SEQ ID NO: 2 and 7), have unexpected results and are not obvious over the prior art. Applicants have compared their invention to the prior art and shown that improved results were found for the specific primer pairs. The specification on pages 24, 26 illustrate that the primers C131F25 and C294R25 do not detect any false positives like the Roche primers. Therefore, the obviousness of the primers has been overcome by the demonstration of unexpected results.

Moreover, the double patenting rejection has been overcome in view of the terminal disclaimer.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*J. Goldberg*  
Jeanine Goldberg  
April 24, 2003

*G. Benzon*  
GARY BENZON, PH.D  
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